IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF HOWARD JORDI, PH.D.

Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants"), hereby submit this Reply in support of Ethicon's Motion to Exclude the Opinions and Testimony of Howard Jordi, Ph.D. ("Motion") [ECF No. 1983] and Memorandum in Support [ECF No. 1984].

I. Any Testimony About Clinical Significance of Degradation Would Be Speculative, Because Dr. Jordi Did Not Analyze Any of the Plaintiffs' Mesh Explants to Establish that These Meshes Degraded to a Clinically Significant Extent.

In its Motion, Ethicon argues that Dr. Jordi's opinions on degradation are unhelpful, because there is no admissible evidence that this alleged degradation is clinically significant. In countering this argument, Plaintiffs do not cite to any scientific literature, expert opinions, or evidence supporting a finding of clinical significance. Instead, the Plaintiffs rely solely on this Court's prior ruling to allow Dr. Jordi to testify in *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473. *See* Pls.' Opp. Defs.' Mot. Exclude Jordi ("Response") at 2 [ECF No. 2186]. However, the *Bellew* decision is distinguishable, because here, unlike *Bellew*, Dr. Jordi never analyzed the Plaintiffs' meshes to determine whether the meshes degraded at all or did so to a clinically significant extent. Because Dr. Jordi cannot reliably opine about the existence or degree of

degradation of any of the Plaintiffs' meshes, any testimony that the Plaintiffs' mesh implants degraded to a clinically significant degree would be mere speculation.

In *Bellew*, Dr. Jordi performed several tests on the plaintiff's mesh explant and opined that the "level of degradation [he observed] will have a *strong impact* on fiber mechanical properties." Mem. Op. & Order at 9–10, *Bellew v. Ethicon Inc., et al.*, No. 2:13-cv-22473 (S.D.W. Va. Nov. 20, 2014) ("*Bellew* Op. & Order"), [ECF No. 265]. Accordingly, Dr. Jordi was able to determine the extent to which Plaintiffs' mesh had degraded.

Here, Dr. Jordi did not test any of the Plaintiffs' meshes and cannot offer any opinions about the level of degradation in the Plaintiffs' meshes. As Dr. Jordi has admitted, not all degradation is clinically significant. Mot. Ex. D, Trial Tr. vol. 8, 151:9–14, *Batiste v. Johnson & Johnson*, No. DC-12-14350 at (Tex. 95th Jud. Dist. Ct. Mar. 21, 2014). Further, Dr. Jordi cannot make any reliable assumptions about the alleged degradation of Plaintiffs' meshes, because his own testing has found Prolene mesh explants that did not degrade. *See* Reply Ex. M, Jordi 8/19/14 Dep. Tr. 133:22–134:18 (testifying about Prolene mesh explants that showed no signs of degradation). Without any admissible evidence as to the level of degradation of the Plaintiffs' meshes, there is no reliable foundation to show that the Plaintiffs' meshes degraded in a clinically significant manner.

Accordingly, Dr. Jordi's opinions on degradation do not fit the facts of these cases, as there is no reliable foundation to show that degradation could or did cause the Plaintiffs' alleged injuries. *See In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 434–35 (S.D.N.Y. 2005) (excluding experts' opinions because there was no reliable basis for determining that allegedly defective drug had reached a clinically significant concentration). *Cf. Johnson & Johnson v. Batiste*, No. 05-14-864-CV, 2015 WL 6751063, at *6 (Tex. App. 2015) (mem. op.) (finding that

Dr. Jordi's degradation opinions could not establish causation because there was no evidence as to the level of degradation necessary to cause injury).

II. Opinions and Testimony Regarding Degradation of Prolene Sutures Is Unfairly Prejudicial Unless Evidence of FDA Actions with Respect to Prolene Sutures Is Admitted.

The Plaintiffs, in arguing that "there is no such animal as opinion preemption" (Resp. at 3), misstate Ethicon's argument with respect to suture degradation evidence. Clearly, if the Plaintiffs were directly alleging that Prolene sutures were defectively designed, these claims would be preempted and Dr. Jordi would not be allowed to opine that Prolene sutures can degrade. Ethicon's argument is that allowing this same testimony in the context of the current consolidated action would unfairly prejudice the Defendants ***unless*** the Defendants are allowed to introduce evidence that, despite this alleged degradation, the FDA expressly found Prolene sutures to be safe and effective for use in humans.

This is not a question of piecemeal application of preemption and is therefore outside the scope of the Court's prior rulings on this issue. Instead, this is a straightforward analysis under Federal Rule of Evidence 403. Unless Dr. Jordi's suture testimony and opinions are excluded, he will be allowed to testify at trial that Prolene sutures can degrade *in vivo*. The jury will likely infer from this testimony that this degradation is somehow clinically significant. This inference is contradicted by the FDA's regulatory actions, which ***conclusively*** establish that *in vivo* degradation of Prolene sutures is not clinically significant. Unless Ethicon is given the opportunity to combat any erroneous inference with evidence of the FDA's regulatory actions—actions that would preempt any state law claims that Prolene sutures were defectively designed—Ethicon will be unfairly prejudiced, and the jury will be confused or misled into thinking that Prolene sutures are defective and, therefore, Prolene mesh must be, too.

Thus, without evidence of FDA actions with respect to Prolene sutures, the probative value of Dr. Jordi's suture testimony and opinions would be substantially outweighed by the risk of unfair prejudice to Ethicon, confusion of the issues, and misleading the jury. These concerns can only be rectified by precluding Dr. Jordi from testifying about or relying on studies on suture degradation ***or*** allowing Ethicon to introduce evidence that the FDA determined that Prolene sutures were safe and effective and that *in vivo* degradation was not clinically significant.

III. Dr. Jordi's Opinions on Mechanical Properties and Environmental Stress Cracking Are Unreliable Because They Are Based Primarily on Unreliable Testing of Non-Party Explants.

In opposing Ethicon's motion to limit Dr. Jordi's opinions on mechanical properties and environmental stress cracking ("ESC"), the Plaintiffs again rely exclusively on the Court's rulings on these issues in *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473.[1] The Court's prior rulings are not applicable, however, because in *Bellew*, Dr. Jordi's opinions were based primarily on his personal testing of Ms. Bellew's explant. Here, Dr. Jordi did not test any of the Plaintiffs' explants, meaning he has no reliable basis to opine as to the mechanical properties of the Plaintiffs' meshes or the susceptibility of these meshes to ESC.

In *Bellew*, the Court specifically noted that Dr. Jordi's opinions on mechanical properties were based on the "numerous tests he performed on Ms. Bellew's mesh explant." *Bellew* Op. & Order at 9. Similarly, Dr. Jordi's ESC opinions were "based on his examination of Ms. Bellew's mesh." *Id.* at 11.

Here, Dr. Jordi did not test or examine any of the Plaintiffs' meshes. As such, any opinions regarding the level of degradation of the Plaintiffs' meshes and the mechanical

[1] Despite the plaintiff designating Dr. Jordi as an expert in *Bellew*, the plaintiff never called him as a witness.

properties of these meshes would be speculative at best. *See Wilkerson v. Bos. Sci. Corp*., No. 2:13-CV-04505, 2015 WL 2087048, at *26 (S.D.W. Va. May 5, 2015) (finding opinions based on speculation inadmissible). Similarly, Dr. Jordi cannot reliably opine that any of the Plaintiffs' mesh fibers actually absorbed fatty acids or cholesterol esters, such that they would be susceptible to ESC.[2]

For these reasons, the Court's rulings in *Bellew* are not controlling, and the Court should exclude Dr. Jordi's opinions and testimony regarding mechanical properties (including brittleness) and environmental stress cracking.

Respectfully submitted,

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[2] The Plaintiffs, citing to a 2010 Clave article, claim that Dr. Jordi's ESC opinions are supported by the peer-reviewed literature. *See* Resp. at 6. As addressed in the Defendants' Memorandum of Law, the Clave article does not actually support the notion that Prolene or polypropylene is susceptible to ESC. Defs.' Mem. at 13 n.4 & Ex. K [ECF No. 1983-11].

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CERTIFICATE OF SERVICE

I certify that on May 16, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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